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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,915	08/15/2001	Ashley J. Birkett	ICC-102.2US 81175	2278
24628	7590	02/03/2004		
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			EXAMINER WORTMAN, DONNA C	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,915	BIRKETT, ASHLEY J.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/20/03 and phone interview 1/22/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above claim(s) 79-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-115 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>1/22/04</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: |

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Applicant's election without traverse of Group I, claims 1-78 in the paper filed 17 October 2002 is acknowledged.

Claims 79-115 are withdrawn from consideration as drawn to non-elected inventions. Claims 1-78 are under examination.

The following rejection is repeated from the Office action mailed 09 January 2004 and expanded:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 63 are indefinite in reciting "comprised of" since it is not clear whether "comprised of" is open or closed claim language, that is, whether "comprised of" is open language equivalent to "comprising" or closed language equivalent to "consisting of." The metes and bounds of the claims are unclear.

Claim 56 is indefinite in reciting "The immunogenic particle according to claim 1" without antecedent in claim 1. It is believed that claim 56 was intended to depend from claim 51. Clarification or correction is needed.

The following rejection is repeated from the Office action mailed 09

January 2004:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 11, 18, 34, 39, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Zlotnick et al. (Proc. Natl. Acad. Sci. 94:9556-9561, 1997), cited on PTO 1449 as reference A29. Zlotnick et al. disclose a truncated hepatitis B virus capsid protein that assembles into particles, lacks the part of the protein that binds nucleic acid, and has a cysteine added at the carboxy terminus that is deemed to anticipate the subject matter of claims 1, 10, 11, 18, 34, 39, 40, and 41, since it is the same as the embodiment of claim 1(a) that has a sequence of at least about 135 residues of the N-terminal 150 HBc amino acid residues, and is the same as the embodiment of claim 18 in which (a) has the optional feature not present, (b) is (ii), (d) (i) is fourteen residues, (d) (ii) is one C-terminal cysteine, and (d) (iii) is zero heterologous amino acids. (See, e.g., page 9556, col. 2, line 8-page 9557, col. 1, line 5, and Fig. 1.) Since the Zlotnick protein is the same as the claimed protein, it necessarily has the same properties as Applicant's protein with respect to stability.

Claims 2-9, 12-17, 19-33, 35-38, and 42-78 are free of the prior art which does not teach or fairly suggest recombinant chimer hepatitis B protein molecules having a peptide-bonded heterologous epitope or a heterologous linker residue for a conjugated

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epitope; containing C-terminus cysteine residue(s) as claimed; and self-assembling into particles that are more stable than particles formed from an otherwise identical HBc chimera that lacks the C-terminal cysteine residue(s) as claimed. Claims limited to this subject matter would be likely to receive favorable consideration once the rejections under 35 USC 112, second paragraph, have been overcome and the provisional obviousness-type double patenting rejections set out below have been resolved. See MPEP 804 I.B.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of copending Application No. 10/082014. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-69 are drawn to the same subject matter, *viz.*, recombinant chimera HBc protein molecules that have

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C-terminal cysteine(s), self-assemble into particles, and have improved particle stability, as are claims 1-69 of 10/082014, differing only in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/080299. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-69 are drawn to the same subject matter, *viz.*, recombinant chimer HBc protein molecules that have C-terminal cysteine(s), self-assemble into particles, and have improved particle stability, as are claims 1-23 of 10/080299, differing only in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following rejection is made in addition to those in the Office action mailed 09 January 2004:

Claims 1-78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over currently pending claims 1-11, 13-17, 19, 20, 22-30, 32-37, 29-43, 45, 46, 48, 49, 51, 53, 54, 56-58 of copending Application No. 09/931325. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-78 encompass the same subject matter, *viz.*, recombinant chimer HBc protein molecules that have C-terminal cysteine(s) and heterologous epitopes, and self-assemble into particles, as do

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claims 1-11, 13-17, 19, 20, 22-30, 32-37, 29-43, 45, 46, 48, 49, 51, 53, 54, 56-58 of 09/931325, differing only in scope.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The period for reply is restarted to begin as of the mailing date of this supplemental Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 571-272-0913. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027 until 26 January 2004, and 571-272-0902 after that date. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw